

# **EXHIBIT 25**

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

Page 1

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

In Re:

Bair Hugger Forced Air Warming  
Products Liability Litigation

This Document Relates To:

All Actions MDL No. 15-2666 (JNE/FLM)

DEPOSITION OF WINSTON T. TAN  
VOLUME I, PAGES 1 - 117  
MARCH 10, 2017

(The following is the deposition of WINSTON  
T. TAN, taken pursuant to Notice of Taking Deposition,  
via videotape, at the offices of Ciresi Conlin L.L.P.,  
225 South 6th Street, Suite 4600, Minneapolis,  
Minnesota, commencing at approximately 9:10 o'clock  
a.m., March 10, 2017.)

## CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

<p style="text-align: right;">Page 94</p> <p>1 If any of your answers require you to relay 2 conversations you had with counsel, I'm objecting on 3 behalf of 3M as privileged. 4 Q. Did you have any conversations with your 5 supervisor -- not with any attorneys, but your 6 supervisor -- regarding the claims in the litigation 7 and any testing that needs to be performed? 8 A. Not without the presence of an attorney. 9 Q. Did you meet with anybody within the 10 company -- and I'm not talking about with an attorney 11 present -- without an attorney present regarding the 12 claims in the litigation and whether or not any 13 testing needs to be performed? 14 A. I don't believe so. 15 (Exhibit 368 was marked for 16 identification.) 17 THE WITNESS: Is there a particular page? 18 MR. FARRAR: I want to go through a lot of 19 this, so if you want to read it real quick -- 20 THE WITNESS: Sure. 21 MR. FARRAR: -- so we can ask questions 22 while we go through it. 23 THE WITNESS: Okay. 24 BY MR. FARRAR: 25 Q. Do you recall --</p>	<p style="text-align: right;">Page 96</p> <p>1 media? 2 A. For the -- once again, for the new warming 3 unit. We were looking at the competitive landscape, 4 if we wanted to put one in when we released the 5 warming unit. 6 Q. So it would have been at your directive or 7 at least the company's directive to use HEPA grade; 8 correct? 9 A. As exploratory. 10 Q. Okay. And Mr. Cuta says, "...the cost of 11 the filter will be more than what you're paying for 12 the current production filter." That would be the 13 filters used in the 750 or 775; correct? 14 A. Not for certain if he meant -- if he used 15 the -- you know, this new design, the difference in 16 media, I'm -- I can't -- 17 Q. Okay. 18 A. -- recall for -- 19 Q. I don't mean to interrupt. 20 A. Yeah. 21 Q. He says "current production filter," which 22 would indicate the ones being produced. Does that 23 mean something essentially different to you? 24 A. It could be like pilot, you know, some 25 samples. It could have been. He probably used some</p>
<p style="text-align: right;">Page 95</p> <p>1 The first e-mail -- and this is in April of 2 2015 -- you send to folks at Pentair. You say, "Would 3 you -- Would you have any updates on the filter 4 discussion we had on April 10th?" 5 Do you recall what filter discussions you 6 had with the folks at Pentair in April 2015? 7 A. I'm sorry. Where was that sentence? 8 Q. The very -- the second page, the very last 9 par -- the very last sentence of the second page. 10 A. Probably -- 11 Perhaps we were developing this new warming 12 unit and we were looking at a filter for this new 13 warming unit we were developing. 14 Q. Okay. Is it your testimony that in April 15 2015 you weren't looking -- that the conversations 16 with Pentair didn't have anything to do with the 17 filters on the 750 or 775? 18 A. I don't believe so. 19 Q. All right. And Craig -- 20 Is it Cuta, C-u-t-a? 21 A. Yes. 22 Q. -- at Pentair responds to you and he says, 23 "Our efforts so far have been around a design using 24 HEPA grade media." 25 Do you know why Pentair was using HEPA grade</p>	<p style="text-align: right;">Page 97</p> <p>1 prototype samples, "production," if he meant -- 2 Yeah. 3 Q. Do you know if you ever got a cost estimate 4 of what it would cost per filter for a HEPA grade 5 filter? 6 A. Let me -- 7 I don't recall if I -- if he let us know the 8 rough size, estimate -- 9 I can't recall -- 10 Q. Okay. 11 A. -- if I received it. 12 Q. We saw earlier in the document that the M20 13 was -- I think it was \$12.83. Do you recall that? 14 MR. GOSS: Eighty-one. 15 MR. FARRAR: Eighty-one. 16 Q. Little under 13 bucks. 17 A. Yes. Yes. 18 Q. Do you recall any estimate that you got on 19 how much a HEPA filter would cost? 20 A. I can't recall. 21 Q. Okay. You don't recall any ballpark numbers 22 at all? 23 A. I don't really recall. Unless there is an 24 e-mail in front of me that lists it, I can't recall -- 25 Q. Okay.</p>

## CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

Page 98

1 A. -- if I received it. I don't recall.  
 2 Q. You e-mailed Mr. Cuta back and you said,  
 3 "Yes, please continue with this path," meaning --  
 4 A. Uh-huh.  
 5 Q. -- continue using the HEPA grade media;  
 6 correct?  
 7 A. Let me see. As exploratory for the new  
 8 warming unit, --  
 9 Q. Sure.  
 10 A. -- that's correct.  
 11 Q. If we go to the first page, four days later  
 12 you e-mail Mr. Cuta again, you say, "Sorry for the  
 13 change in project scope. Management would rather have  
 14 us look into how we can take costs out of the current  
 15 rectangular filter."  
 16 I read that correctly?  
 17 A. Yes. Yes. Yes.  
 18 Q. Okay. So who did you speak with at  
 19 management who told you that they want to take costs  
 20 out of the current rectangular filter?  
 21 A. Yeah. So the cost always --  
 22 Probably to the frame that Chris Miller, the  
 23 project manager, and probably my supervisor at the  
 24 time, --  
 25 Q. Okay.

Page 99

1 A. -- so we were looking at the -- the -- the  
 2 frame of the -- the filter.  
 3 Q. Does the "take cost out" also relate to the  
 4 efficiency of the filter?  
 5 A. No.  
 6 Q. All right. On --  
 7 So that was on April 27th. On July 15th you  
 8 forward that same e-mail to Daniel Doran; correct?  
 9 A. Yes. At the time I was moving on and he was  
 10 taking over.  
 11 Q. And he takes over and he -- he e-mails Craig  
 12 and he says, "I -- I received your contact information  
 13 from Winston Tan (see below)."  
 14 What happened between April 28th and July  
 15 15th where you were no longer in the filter section of  
 16 the warming unit?  
 17 A. I believe I moved on to a different project.  
 18 Q. What project, do you recall?  
 19 A. It was just front-end work.  
 20 Q. Sorry?  
 21 A. I'm sorry. Front-end.  
 22 Q. What does that mean?  
 23 A. Front-end engineering, front-end innovation,  
 24 looking at --  
 25 Q. New products.

Page 100

1 A. Correct.  
 2 Q. Okay. Did you have any disagreements with  
 3 management regarding the filter selection that  
 4 prompted this move?  
 5 A. I don't believe so, no.  
 6 Q. What prompted the move from where you were  
 7 with the warming unit to the front-end area?  
 8 A. Oh. I believe we hired Dan Doran, and that  
 9 was his -- that was -- the intent was that was his  
 10 role, he was going to be the engineer on it, and --  
 11 because it's always been my preference to work on  
 12 front-end.  
 13 Q. Okay. So this was a choice that you made.  
 14 A. Correct.  
 15 Q. Do you remember what type of products you  
 16 worked on from July 2015 to when you left the company  
 17 a year later or so?  
 18 A. Yeah. We looked at automating fluid-warming  
 19 lines, looked at some core temperature monitoring  
 20 devices, and some prewarming, like warming in the pre-  
 21 op.  
 22 Q. Was that forced air or a different type of  
 23 modality?  
 24 A. In white space. We looked at everything.  
 25 Q. Okay.

Page 101

1 (Exhibit 369 was marked for  
 2 identification.)  
 3 THE WITNESS: Okay.  
 4 BY MR. FARRAR:  
 5 Q. I'm looking at an e-mail marked as Exhibit  
 6 369 from July of 2015, and specifically the one July  
 7 23rd from Mr. Balthazor to you and Jennifer Yi. Do  
 8 you see that?  
 9 A. Yes.  
 10 Q. And Jared says, "I informed Sarah we are no  
 11 longer interested in changing the filter at this  
 12 time." And they're referring to the Porous Media M20;  
 13 correct?  
 14 A. Yes.  
 15 Q. Do you know why the decision was made in  
 16 July 23rd, 2015 to stop looking at different filters  
 17 to be used in the Bair Huggers?  
 18 A. I do not recall.  
 19 Q. Was it related to litigation?  
 20 MR. FRESCH: Object to form.  
 21 MR. GOSS: And again, if your answer  
 22 requires you to relay any conversations you had with  
 23 3M counsel, we would assert privilege over that.  
 24 A. It was -- I had --  
 25 We had conversations with Maureen Harms,

26 (Pages 98 to 101)

## CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

<p style="text-align: right;">Page 106</p> <p>1 my supervisor.  2 Q. Okay. So the --  3 In other words, what's happening in  4 marketing isn't necessarily always relayed to you;  5 correct? Different -- different unit.  6 A. Yes.  7 Q. So what's happening with the competitors in  8 the marketplace you might or may not be aware of.  9 Fair enough?  10 A. That would be fair.  11 Q. So it would not be unusual for either your  12 supervisor or the folks in marketing to come to you  13 and say, "Why don't you guys try to design a way to  14 keep the hose clean," without you having the full  15 information or knowledge as to why you're doing that.  16 Is that fair?  17 A. Yes. Fair.  18 Q. Same way, your supervisor or somebody else  19 could come to you and say, "Let's look at a way that  20 we could increase the efficiency of the filter," and  21 you may or may not know exactly why you're doing that,  22 you're just going to go do it; right?  23 A. For that situation, I don't believe anybody  24 has --  25 That one I was told for. That was</p>	<p style="text-align: right;">Page 108</p> <p>1 different filter ideas; correct?  2 A. Yes.  3 Q. Okay. And these filters, insertable filters  4 into the hose, these are all ideas that you -- were  5 technologically feasible at the time. Fair enough?  6 MR. GOSS: Object to form.  7 MR. FRESCH: Object to form.  8 A. Yes.  9 Q. Have you ever heard discussions within the  10 company about a distal filter on the hose?  11 A. I do not recall.  12 Q. If I talked to you about Project Ducky, is  13 that something that you would have any familiarity  14 with?  15 A. I know the name, but I was not involved.  16 Q. Do you know what Project Ducky was, what it  17 involved?  18 A. Not really.  19 Q. Okay. If we turn to page seven --  20 And the number on the bottom left is really  21 faint.  22 A. Oh, yes. Yes.  23 Q. This is kind of where we get to the second  24 idea of modular; correct? Second ideation.  25 A. Yes.</p>
<p style="text-align: right;">Page 107</p> <p>1 competitive landscape.  2 Q. Okay. That one was specifically told to  3 you, but in terms of why keeping the hose clean, you  4 didn't have a specific reason as to why you were doing  5 it, just doing it.  6 A. Other than there was competitors that had --  7 Q. Okay. And the --  8 You and your team come up with three  9 concepts: an insertable filter, modular disposable  10 hose, or self-cleaning system; correct?  11 A. And these were really-out-of-this-world type  12 of exploratory.  13 Q. Okay. These are just -- yeah. These are  14 ideas that smart guys in a room come up with; right?  15 A. Yeah. This was just white space.  16 Q. Right.  17 But these are ideas that are feasible;  18 right? I mean you -- you could design -- design these  19 types of systems; correct?  20 MR. GOSS: Object to form.  21 A. No, not all.  22 Q. Okay. Well let's talk about the --  23 I'm not going to go through this in -- in  24 detail, but the insertable filter --  25 And you've got a handful of pages here of</p>	<p style="text-align: right;">Page 109</p> <p>1 Q. What --  2 Can you define what "modular" meant in terms  3 of a way to attempt to try to keep the hose clean?  4 A. I think "modular" would then coincide with  5 "insertable," how -- if you had an insertable filter,  6 how would you insert it into the hose, which is to say  7 mechanical way to do it.  8 Q. How would --  9 So modular is just really a -- a way to get  10 the filter into the hose?  11 A. I believe so.  12 Q. Okay. And -- and feel free to flip through.  13 A. I believe so. From --  14 It's been a while since I've seen these  15 drawings, so --  16 Yeah. Possibly. Yeah.  17 Q. Okay. And if we flip over to page -- I  18 believe it starts -- 13, starts the "Self-Cleaning/  19 Contained System."  20 A. Yes.  21 Q. And you have number "9. Check Engine Light."  22 Do you see that?  23 A. Yes.  24 Q. That means basically when the filter is --  25 needs to be changed, some light comes on that tells</p>

# **EXHIBIT 26**

CONFIDENTIAL

Page 1

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

In Re:

Bair Hugger Forced Air Warming  
Products Liability Litigation

This Document Relates To:

All Actions MDL No. 15-2666 (JNE/FLM)

DEPOSITION OF GARY L. HANSEN

VOLUME I, PAGES 1 - 316

NOVEMBER 2, 2016

(The following is the deposition of GARY L.  
HANSEN, taken pursuant to Notice of Taking Deposition,  
via videotape, at the offices of Ciresi Conlin L.L.P.,  
225 South 6th Street, Suite 4600, Minneapolis,  
Minnesota, commencing at approximately 9:30 o'clock  
a.m., November 2, 2016.)

## CONFIDENTIAL

<p style="text-align: right;">Page 198</p> <p>1 statistically significant; correct?</p> <p>2 A. According to the paper.</p> <p>3 Q. Okay. Now the study that was done in -- was</p> <p>4 it Sweden? Where was the study done that Sessler --</p> <p>5 A. Netherlands.</p> <p>6 Q. Netherlands. That's right. Netherlands.</p> <p>7 That had a smaller sample size too; didn't</p> <p>8 it?</p> <p>9 A. We used the sample size which was consistent</p> <p>10 with the DIN standard.</p> <p>11 Q. I didn't ask that. It was a small sample</p> <p>12 size; wasn't it?</p> <p>13 MR. GORDON: Object to the form of the</p> <p>14 question, argumentative.</p> <p>15 A. I think "small" is subjective.</p> <p>16 Q. Five data points?</p> <p>17 A. Yes.</p> <p>18 Q. Isn't that right?</p> <p>19 A. Yes.</p> <p>20 Q. And Dr. Sessler said that it looks to him</p> <p>21 like if you'd used more, it would have been</p> <p>22 statistically significant, the difference.</p> <p>23 MR. GORDON: Object to the form of the</p> <p>24 question.</p> <p>25 Q. Didn't he?</p>	<p style="text-align: right;">Page 200</p> <p>1 Q. But that's what he said.</p> <p>2 A. He --</p> <p>3 That's what he said.</p> <p>4 Q. Thank you.</p> <p>5 MR. GORDON: Object to the form of the</p> <p>6 question.</p> <p>7 Q. And the reason that study was done was for a</p> <p>8 legal strategy; isn't that right?</p> <p>9 A. I disagree. It was done to have a direct</p> <p>10 scientific answer to the charges of air filtra -- or</p> <p>11 of particulates in the operating room.</p> <p>12 (Exhibit 11 was marked for</p> <p>13 identification.)</p> <p>14 BY MR. CIRESI:</p> <p>15 Q. Now this is a series of e-mails that have</p> <p>16 been marked as Exhibit 11. The last is from Teri</p> <p>17 Woodward-Sides to you with carbon copies to the top</p> <p>18 guy, Mr. Maharaj, to Bob Buehler, to Jana Stender.</p> <p>19 Who is Jana Stender?</p> <p>20 A. She was the director of marketing.</p> <p>21 Q. Director of marketing. Okay.</p> <p>22 And Bob Gagne, who is that?</p> <p>23 A. He was a consultant to the company.</p> <p>24 Q. What kind of consultant?</p> <p>25 A. I think he was a marketing consultant.</p>
<p style="text-align: right;">Page 199</p> <p>1 A. He may have said that in an e-mail.</p> <p>2 Q. Yes. And the difference was somewhere</p> <p>3 around five to one; wasn't it?</p> <p>4 MR. GORDON: Object to the form of the</p> <p>5 question, lack of foundation.</p> <p>6 Q. If you recall. Something like a hundred</p> <p>7 and --</p> <p>8 A. Are we talking about the relative</p> <p>9 difference --</p> <p>10 Q. Yes.</p> <p>11 A. -- between --</p> <p>12 Q. A hundred -- a hundred and eighty-six to --</p> <p>13 The average of the five data points was</p> <p>14 something like 186 to 28 or something like that.</p> <p>15 A. The important thing was that there was a</p> <p>16 large log reduction of both to a highly significant</p> <p>17 degree so that the differences between them were less</p> <p>18 important.</p> <p>19 Q. What he said was that if there had been more</p> <p>20 tests -- more data points, it would have been</p> <p>21 statistically significant.</p> <p>22 MR. GORDON: Object to the form of the</p> <p>23 question.</p> <p>24 Q. And that's what he said; isn't that right?</p> <p>25 A. And that's hard to predict even for him.</p>	<p style="text-align: right;">Page 201</p> <p>1 Q. Marketing. Okay. So you had two marketing</p> <p>2 people.</p> <p>3 Bob Buehler, what was his title?</p> <p>4 A. He was in charge of the sales force. I</p> <p>5 don't know --</p> <p>6 Q. Sales.</p> <p>7 A. I don't know what his title was.</p> <p>8 Q. Okay. So you got sales, marketing,</p> <p>9 marketing, the CEO.</p> <p>10 And Teri Sides -- or Woodward-Sides was who?</p> <p>11 A. She was the vice president of --</p> <p>12 Q. International sales?</p> <p>13 A. -- product development and marketing, if I</p> <p>14 get it right.</p> <p>15 Q. Vice president of --</p> <p>16 A. Product development and marketing.</p> <p>17 Q. Product development and marketing.</p> <p>18 And then you as head of research and</p> <p>19 development; correct?</p> <p>20 A. Yes.</p> <p>21 Q. Date, 4-23-2010; correct?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. Was Teri Woodward-Sides a forthright</p> <p>24 person?</p> <p>25 A. Yes, I would say so.</p>



## CONFIDENTIAL

<p style="text-align: right;">Page 226</p> <p>1 Q. How long does an operation take for hip 2 replacement? 3 A. An hour or more. 4 Q. An hour or more. 5 How about for a knee replacement? 6 A. Again, a lengthy period of time. 7 Q. An hour or more; right? Isn't that right? 8 A. To the best of my knowledge. 9 Q. So this test that you did was one-60th of 10 the time that it would take for an operation with no 11 complications. 12 A. May I explain why we chose that -- that 13 interval? 14 Q. I just want to know if the ans -- if I'm 15 correct. 16 A. Repeat the question. 17 Q. One-60th of the time it takes -- 18 A. According to the math -- 19 Q. -- for an operation without any 20 complications. 21 A. If the operation took an hour, then that's 22 what the math says. 23 Q. Okay. Now you want to tell me why you chose 24 one minute -- 25 A. Right.</p>	<p style="text-align: right;">Page 228</p> <p>1 Q. Is that -- is that the difference? 2 A. The test was a controlled test under 3 controlled circumstances. If you wanted to do a 4 realistic test with multiple people moving around the 5 operating room under actual conditions of surgery, it 6 would have been a different study. It isn't the study 7 we chose to do. 8 Q. Right, I know you didn't. Because the DIN 9 standard doesn't consider statistical standards; does 10 it? 11 MR. GORDON: Object to the form of the 12 question, move to strike counsel's commentary. 13 MR. BREWER: Objection, foundation. 14 A. It does -- 15 Q. If you know. 16 A. It does consider statistical treatment of 17 the data. 18 I did recall asking Dr. Kuelpmann why five 19 standards, and I believe he told me that five was 20 sufficient to get a decent variance in the data for 21 their test purposes. 22 Q. Let's look at your e-mail to the doctors on 23 Exhibit 12, the last paragraph. "Bear in mind the DIN 24 1946 is intended to verify the effectiveness of 25 operating room filtration. Therefore, it's cut-and-</p>
<p style="text-align: right;">Page 227</p> <p>1 Q. -- for the measurement. 2 A. The five successive one-minute measurements 3 were part of the DIN standard, which had been used in 4 multiple operating rooms throughout the world for 5 validating operating room quality, so they had 6 determined ahead of time that five measurements were 7 sufficient to get a good sample of particulate 8 measurements in an operating room that wasn't being 9 occupied by people at the time, and that's how they 10 test operating rooms under the standard. 11 Q. That's for an operating room. Here we're 12 talking about a machine in the operating room which is 13 sucking up air from the floor which is dirty, as 14 you've acknowledged, is going through the machine 15 heated, out the hose, deposited on the person during 16 an operation that takes an hour and it's going 17 continuously. 18 MR. GORDON: Object to the form of the 19 question, move to strike counsel's commentary. 20 Q. This doesn't relate to the one-minute 21 intervals to see whether or not the air quality is 22 good in the operating room with people doing nothing. 23 A. That's not a question. 24 MR. GORDON: Same objection, move to strike 25 counsel's speech.</p>	<p style="text-align: right;">Page 229</p> <p>1 dried in its requirements; either an OR meets the 2 standard or it does not. The authors did not envision 3 making comparisons, so a -- so a statistical treatment 4 is missing from the document. For the purposes of 5 pass/fail, PE is calculated using the single worst 6 one-minute sample of the collection." 7 Did I read that correctly? 8 A. From memory, I think that's what the 9 standard said. 10 Q. And -- and -- and I read it correctly; 11 correct? 12 A. Yes, you did. 13 Q. And that is the standard; isn't it? 14 A. Yes. 15 Q. Thank you. 16 And your e-mail to Drs. Olmstead and 17 Sessler, which is Exhibit No. 12, was in November, and 18 it would have been after you had had other discussions 19 with Mis -- or Dr. Kuelpmann; correct? 20 A. April to November, yes. 21 Q. And you had been talking to Kuelpmann and 22 trying to figure out what the DIN was up to that point 23 in time; weren't you? 24 A. Yes, trying to understand the data and also 25 to get the report written, which took a long period of</p>

# **EXHIBIT 27**

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

Page 1

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

In Re:

Bair Hugger Forced Air Warming  
Products Liability Litigation

This Document Relates To:

All Actions MDL No. 15-2666 (JNE/FLM)

DEPOSITION OF DR. DANIEL SESSLER  
VOLUME I, PAGES 1 - 152  
JANUARY 11, 2017

(The following is the deposition of DR.  
DANIEL SESSLER, taken pursuant to Notice of Taking  
Deposition, via videotape, at the Cleveland Clinic,  
P Building, Conference Room P77-013, 2070 East 90th  
Street, Cleveland, Ohio, commencing at approximately  
10:11 o'clock a.m., January 11, 2017.)

## CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

<p style="text-align: right;">Page 62</p> <p>1 A. That's -- that's called data selection; it's 2 a type of research fraud. 3 Q. Would you agree -- 4 A. You have to look at all the data. 5 Q. Would you agree with me that any substantial 6 increase would concern clin -- clinicians? 7 A. Average increase, not -- not results from 8 one run and one circumstance. 9 Q. Would you agree with me that any substantial 10 increase would concern clinicians? 11 MR. GORDON: Object to the form of the 12 question, also lack of foundation. 13 A. Any substantial increase in average values 14 over all conditions would concern people. 15 Q. Okay. And then you say in the third 16 paragraph, "Possibly the best statistical approach 17 would be an ANOVA with cover type...;" correct? 18 A. Yes. 19 Q. And that's in fact what you guys have ended 20 up doing; correct? 21 A. Correct. 22 Q. Okay. And ANOVA is basically analysis of 23 variance; right? 24 A. Yes. 25 Q. And then you say, "But perhaps it would be</p>	<p style="text-align: right;">Page 64</p> <p>1 the machine that was used in Amersfoort might have 2 been a used one versus a new one? 3 A. No. 4 Q. Or that there was different protocols for 5 how they clean the OR? 6 A. No. But it's not relevant to this study, 7 which used artificial particles. This had nothing to 8 do with bacteria. 9 Q. Well I think we've already established you 10 don't know whether the Bair Hugger sucks in 11 particulates from off the floor and spews them out 12 into the surgical site; right? 13 MR. GORDON: Object to the form of the 14 question. 15 A. I don't think that's relevant to this study 16 where there are 20 million particles floating around 17 that are deliberately introduced. 18 Q. So it wouldn't be of clinical interest to 19 you. 20 A. You -- you're confusing two different 21 circumstances. One is whether forced-air warmers pick 22 up bacteria, retain bacteria or somehow eject 23 bacteria. If they do, that's a problem. A second 24 issue, which is what this paper is about, is whether 25 warm air interferes with the laminar flow column. Has</p>
<p style="text-align: right;">Page 63</p> <p>1 best to consider the hospitals together since that 2 isn't really a factor of interest; and the cover type 3 could be unpaired." Do you see that? 4 A. Uh-huh. Yes. 5 Q. And in fact what you were describing there 6 is rather than show the results from the two hospitals 7 separately, you were going to group them together for 8 the purposes of the paper; right? 9 A. Yes, because it -- that's the way it should 10 have been done. That's -- that's the correct way of 11 handling these data. 12 Q. Why is it the correct way of handling these 13 data? 14 A. Because the two hospitals together 15 characterize the general case better than either 16 hospital alone. 17 Q. Well you know that ORs are different; right? 18 A. Sure. 19 Q. Okay. That can be a confounding factor; 20 right? 21 A. Could be. 22 MR. GORDON: Object to the form of the 23 question. 24 Q. Could be a confounding factor. 25 Did you do any investigation as to whether</p>	<p style="text-align: right;">Page 65</p> <p>1 nothing to do with bacteria. 2 Q. Okay. And you -- you -- 3 I think we've established this. You're not 4 an expert on laminar flow or how particulates move in 5 the environment; right? 6 A. I'm not. 7 Q. So you -- you basic -- 8 Did you ask anybody why it was that the 9 Amersfoort data appeared so different in terms of the 10 particulate counts? 11 MR. GORDON: Object to the form of the 12 question. 13 A. I don't remember. 14 Q. Was it of interest to you? 15 A. Absolutely. 16 Q. What do you recall doing in connection with 17 that data? 18 A. When you do multicenter studies, it's 19 absolutely routine and normal for the results to 20 differ in the various centers. You -- you expect that 21 just by random motion. And it's also true that the 22 centers are truly different; they have different 23 operating rooms, different anesthesia, different 24 protocols, so you expect real differences among sites 25 in a multicenter study. But you do a multicenter</p>

## CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

<p style="text-align: right;">Page 66</p> <p>1 study to enhance generalizability. You take all the</p> <p>2 results you have and you put them together and you</p> <p>3 present the average because that best characterizes</p> <p>4 what you know, and that's what we did here.</p> <p>5 Q. And in this case you did five samples, five</p> <p>6 runs five minutes each in two hospitals; correct?</p> <p>7 A. Yes.</p> <p>8 Q. And in fact you noted here that there were</p> <p>9 only five measurements; right?</p> <p>10 A. Correct.</p> <p>11 Q. So you're standing behind your proposition</p> <p>12 that this is not an under -- underpowered study;</p> <p>13 correct?</p> <p>14 MR. GORDON: Object to the form of the</p> <p>15 question.</p> <p>16 A. Correct.</p> <p>17 Q. Could pooling the data from Amersfoort and</p> <p>18 Utrecht confound the data?</p> <p>19 A. No.</p> <p>20 Q. Why not?</p> <p>21 A. "Confounding" has a specific meaning, has to</p> <p>22 be something that's related to exposure and outcome.</p> <p>23 I don't see how pooling induces confounding.</p> <p>24 Q. Now I think we talked about this before, but</p> <p>25 Gary Hansen did the first draft; is that right?</p>	<p style="text-align: right;">Page 68</p> <p>1 draping around the OR table, and also perhaps due to</p> <p>2 differences in the laminar flow systems." Do you see</p> <p>3 that?</p> <p>4 A. I do.</p> <p>5 Q. And there was a deleted box beside that, and</p> <p>6 what was deleted is "The significantly higher counts</p> <p>7 seen with the blanket model 635 reflected conditions</p> <p>8 at OR Amersfoort" or "A..." Do you see that?</p> <p>9 A. I see it, yes.</p> <p>10 Q. Okay. Who made the decision to delete from</p> <p>11 this transcript that there had been significantly</p> <p>12 higher counts seen with the underbody blanket at the</p> <p>13 Amersfoort hospital?</p> <p>14 A. Well, whoever edited the document.</p> <p>15 Q. Do you know if that was Mr. Hansen at 3M?</p> <p>16 A. I have no idea who was editing at this</p> <p>17 point.</p> <p>18 Q. Okay. Was that something that you had</p> <p>19 drafted originally, that you had found significantly</p> <p>20 higher counts seen with the blanket model 635 in</p> <p>21 Amersfoort?</p> <p>22 A. I'm not sure I understand the question.</p> <p>23 Q. My question is: Do you know whether you</p> <p>24 were the person who originally put in the draft that</p> <p>25 there had been significantly higher counts seen with</p>
<p style="text-align: right;">Page 67</p> <p>1 A. Yes.</p> <p>2 Q. And then Dr. Olmstead took a crack at it; is</p> <p>3 that right?</p> <p>4 A. Yes.</p> <p>5 Q. And then you edited it; correct?</p> <p>6 A. "Edited" is a generous term. Virtually</p> <p>7 every word in the published manuscript was mine.</p> <p>8 Q. I've handed you, Dr. Sessler, what's been</p> <p>9 previously marked as Deposition Exhibit 79, which is a</p> <p>10 marked-up draft of your study which eventually was</p> <p>11 published and has been previously marked as (Belani)</p> <p>12 Exhibit 16; correct?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. And you were part of this editing</p> <p>15 process; correct?</p> <p>16 A. Yes.</p> <p>17 Q. If we can take a look at draft -- the draft</p> <p>18 page seven, which bears Bates number 50592, and if we</p> <p>19 can look at the middle paragraph starting with "We</p> <p>20 found..."</p> <p>21 A. Yes.</p> <p>22 Q. Okay. Midway down there there is a section</p> <p>23 which in this draft reads, "There were noticeable</p> <p>24 differences in the results between the two operating</p> <p>25 rooms, probably the result of small differences in</p>	<p style="text-align: right;">Page 69</p> <p>1 the underbody blanket at Amersfoort hospital?</p> <p>2 A. I have no idea. Sorry.</p> <p>3 Q. You don't recall.</p> <p>4 A. Not even vaguely. This is from when, 2011,</p> <p>5 and this was years before that.</p> <p>6 Q. Well if you were the one who put it in,</p> <p>7 presumably you -- you put it in originally because you</p> <p>8 thought that would be of interest to clinicians;</p> <p>9 correct?</p> <p>10 MR. GORDON: Object to the form of the</p> <p>11 question, lack of foundation.</p> <p>12 A. We don't know that I put it in.</p> <p>13 Q. Well it's consistent with the e-mail</p> <p>14 exchange we just went through; correct?</p> <p>15 MR. GORDON: Object to the form of the</p> <p>16 question.</p> <p>17 A. It requires supposition.</p> <p>18 Q. Well would you agree that this statement is</p> <p>19 consistent with your -- the deleted statement is</p> <p>20 consistent with your statement as reflected in the</p> <p>21 e-mails we just went through, Exhibit 12?</p> <p>22 MS. DIFRANCO: Here.</p> <p>23 (Document handed to the witness.)</p> <p>24 A. The statement seems consistent with the</p> <p>25 data. Who put it in, who took it out, I have no idea.</p>

# EXHIBIT 28

CONFIDENTIAL

Page 1

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

In Re:

Bair Hugger Forced Air Warming  
Products Liability Litigation

This Document Relates To:

All Actions MDL No. 15-2666 (JNE/FLM)

DEPOSITION OF JANA M. STENDER

VOLUME I, PAGES 1 - 182

DECEMBER 9, 2016

(The following is the deposition of JANA M.  
STENDER, taken pursuant to Notice of Taking  
Deposition, via videotape, at the offices of Ciresi  
Conlin L.L.P., 225 South 6th Street, Suite 4600,  
Minneapolis, Minnesota, commencing at approximately  
9:08 o'clock a.m., December 9, 2016.)

## CONFIDENTIAL

<p style="text-align: right;">Page 174</p> <p>1 Q. I've handed you what's been marked as 199.  2 It's Bates labeled 575251.  3 Did you have a chance to review that?  4 A. I did.  5 Q. All right. And you see where -- where Dr.  6 Sessler is e-mailing Gary Hansen in July of 2011;  7 correct?  8 A. Yes.  9 Q. It's talking about the manuscript being  10 submitted, but it's the next paragraph that I'm  11 interested in. Do you see where he says, "I'm glad 3M  12 is seriously considering a true contamination study.  13 That is the only type of study that will put this  14 issue to bed."  15 Did I read that correctly?  16 A. Yes.  17 Q. And that was eventually forwarded on to you  18 by Mr. -- or Dr. Hansen; correct?  19 A. Yes.  20 Q. So in 2011 you knew what you considered a  21 KOL in this area, in this topic, his opinion was there  22 has never been a true contamination study; correct?  23 MS. GASE: Objection, form, mischaracterizes  24 the document.  25 A. He doesn't say there's never been a true</p>	<p style="text-align: right;">Page 176</p> <p>1 MR. FARRAR: Yeah.  2 (Discussion off the record.)  3 BY MR. FARRAR:  4 Q. Did you draft the war games notes?  5 A. I don't know. I know John Rock was in  6 charge of that. He had led the war games exercises.  7 Q. You just don't know who actually drafted it?  8 A. It's a recap.  9 Q. Okay.  10 A. I -- I don't know who recapped everything.  11 Q. Would this be like a brainstorming session  12 where people would be in a room together and  13 discussing the different issues?  14 A. Again, this was part of the 3M strategic  15 planning process, and so they specifically asked us to  16 look at any factors that would affect the business  17 going forward.  18 Q. Okay. Were you involved in the meetings or  19 whatever took place to create the war games document?  20 A. I was involved in some war games sessions.  21 I can't speak if I was involved in this particular  22 session.  23 Q. Okay. If we look at it, the very first  24 section is "Overall Nightmares;" correct?  25 A. That's correct.</p>
<p style="text-align: right;">Page 175</p> <p>1 contamination study. He said, "I -- I'm glad 3M is  2 seriously considering a true contamination study."  3 Q. Because it's the only type of study that  4 will put the issue to bed.  5 A. That's what this note says, yes.  6 Q. So if there had already been one done, well,  7 we would have already put this issue to bed; right?  8 MS. GASE: Object to form.  9 A. He says this -- you know, this is the only  10 type of study this will push -- put the issue to bed.  11 Q. As your personal knowledge, no true  12 contamination study has ever been done; correct? 3M  13 didn't do that; correct?  14 A. I don't personally know if a true  15 contamination study --  16 I don't know what "true contamination"  17 entails, but I -- I don't personally know.  18 Q. Did you ask Dr. Hansen, "What does Dr.  19 Sessler mean by 'a true contamination study?'"  20 A. I don't know that I did. I don't recall.  21 Q. If we would, Exhibit 28, please.  22 Do you recall drafting and sending the war  23 game notes on March 17th, 2011?  24 MS. GASE: Could we go off the record a  25 second?</p>	<p style="text-align: right;">Page 177</p> <p>1 Q. So that was --  2 This would be things that would be overall,  3 in the grand scheme of things, detrimental to the Bair  4 Hugger business. Fair enough?  5 A. That's the way we characterized it.  6 Q. The next one is "Contamination/ABAD;"  7 correct?  8 A. That's the header, yes.  9 Q. This would be stuff that is negative to Bair  10 Hugger, not in an overall sense but much more specific  11 to issues relating to contamination or ABAD; correct?  12 MS. GASE: Objection, form.  13 A. I don't know for certain given what I read  14 here, but presumably, yes, contamination and Augustine  15 Biomedical + Design.  16 Q. And if we go down towards the bottom, four  17 up from the top -- from the bottom I mean, "Someone  18 does a real study on FAW &amp; contamination;" correct?  19 A. That's what it says.  20 Q. So that would be a nightmare scenario for  21 3M, is if somebody actually conducted a real study on  22 forced-air warming and contamination.  23 MS. GASE: Objection, mischaracterizes the  24 document.  25 A. It's not listed as a nightmare scenario,</p>



## CONFIDENTIAL

Page 178

1 it's listed as a Contamination/Augustine Biomedical  
 2 scenario.  
 3 Q. Right. These are all negative things that  
 4 come out of contamination. We have the overall  
 5 nightmares and the nightmares that come out of things  
 6 related to contamination and ABAD; correct?  
 7 A. Not correct.  
 8 Q. All right.  
 9 A. It's not listed as nightmares. These are  
 10 factors that are related to contamination and  
 11 Augustine Biomedical, not nightmares.  
 12 Q. Everything under Contamination/ABAD would be  
 13 bad for 3M; correct?  
 14 A. I would have to read every item.  
 15 Q. Please do.  
 16 Are they all negative things that could  
 17 happen to the company?  
 18 A. I wouldn't characterize them as negative,  
 19 but I do characterize them as scenarios that could  
 20 impact, yes.  
 21 Q. These are all things that could happen that  
 22 would negatively impact the sale of Bair Hugger;  
 23 correct?  
 24 A. I don't know, again, that I would  
 25 characterize everything as negative, but certainly

Page 179

1 could have impact on the business.  
 2 Q. Which ones would you not characterize as  
 3 negative?  
 4 A. I -- I think --  
 5 You know, I can give you an example.  
 6 "Impact of champions in market," that wouldn't  
 7 necessarily be negative, it would just be something  
 8 that happens.  
 9 Q. Okay. So that's one. Any others?  
 10 A. So let me -- let me understand. You want me  
 11 to articulate in my perspective --  
 12 Q. Any -- anything under Contamination/ABAD  
 13 that you believe is not necessarily a negative, would  
 14 not have a negative impact on the company.  
 15 A. I would characterize these as areas of  
 16 concern, certainly. They're all possibilities, and  
 17 that's what this exercise was intended to do.  
 18 Q. Okay. So one area of concern would be "ABAD  
 19 issues contamination test kits to orthos around the  
 20 country;" correct?  
 21 A. That is something that's stated here in the  
 22 recap.  
 23 Q. Obviously, a -- a negative would be a  
 24 "Definitive study showing FAW as source of SSI;"  
 25 correct?

Page 180

1 A. I'm sorry, what was --  
 2 Okay. What was your question again? I'm  
 3 sorry.  
 4 Q. A definitive study showing forced-air  
 5 warming as a source of surgical-site infection, that  
 6 would be a negative outcome; correct?  
 7 A. That would have potential impact on the  
 8 business, yes.  
 9 Q. Okay. And that's the point, is everything  
 10 under Contamination/ABAD are things that could have  
 11 potential negative impact on the sales of Bair Huggers  
 12 or the company; correct?  
 13 MS. GASE: Objection, form.  
 14 A. Potential impact, yes.  
 15 MR. FARRAR: Okay. Okay, Ms. Stender, I  
 16 think I'm done, but let me take a quick break and  
 17 confer real quick.  
 18 THE WITNESS: Okay.  
 19 THE REPORTER: Off the record, please.  
 20 (Recess taken.)  
 21 MR. FARRAR: All right, Ms. Stender, I don't  
 22 have any more questions. I appreciate your time.  
 23 THE WITNESS: Thank you.  
 24 THE REPORTER: Off the record, please.  
 25 (Deposition concluded.)

Page 181

1 C E R T I F I C A T E  
 2 I, Richard G. Stirewalt, hereby certify that  
 3 I am qualified as a verbatim shorthand reporter, that  
 4 I took in stenographic shorthand the deposition of  
 5 JANA M. STENDER at the time and place aforesaid, and  
 6 that the foregoing transcript is a true and correct,  
 7 full and complete transcription of said shorthand  
 8 notes, to the best of my ability.  
 9 Dated at Minneapolis, Minnesota, this 15th  
 10 day of December, 2016.

17 RICHARD G. STIREWALT  
 18 Registered Professional Reporter  
 19 Notary Public  
 20  
 21  
 22  
 23  
 24  
 25

46 (Pages 178 to 181)

# EXHIBIT 29

CONFIDENTIAL

Page 1

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

In Re:

Bair Hugger Forced Air Warming  
Products Liability Litigation

This Document Relates To:

All Actions MDL No. 15-2666 (JNE/FLM)

DEPOSITION OF TROY W. BERGSTROM

VOLUME I, PAGES 1 - 259

NOVEMBER 18, 2016

(The following is the deposition of TROY W.  
BERGSTROM, taken pursuant to Notice of Taking  
Deposition, via videotape, at the offices of Ciresi  
Conlin L.L.P., 225 South 6th Street, Suite 4600,  
Minneapolis, Minnesota, commencing at approximately  
9:04 o'clock a.m., November 18, 2016.)

## CONFIDENTIAL

Page 66

1 like to go over some of those, kind of switch topics.  
 2 A. Okay.  
 3 Q. And I'm going to be handing you some  
 4 scientific studies, and we can go ahead and mark them  
 5 as exhibits. I'm -- I'm really only giving you for --  
 6 to refresh your --  
 7 You need to understand what study I'm  
 8 talking about.  
 9 A. Okay.  
 10 Q. And I want you to understand I'm not trying  
 11 to go at you with science or any of those sorts of  
 12 things. I just want to understand your familiarity.  
 13 And so the first one is -- that I'm going to hand  
 14 you --  
 15 MR. BANKSTON: Go ahead and mark that.  
 16 MS. AHMANN: And again, do you have any  
 17 copies of these?  
 18 MR. BANKSTON: I do not. I just have one.  
 19 I hadn't -- really didn't intend to mark these in as  
 20 an exhibit. If you'd like me to make copies of each  
 21 of these, I can.  
 22 (Exhibit 91 was marked for  
 23 identification.)  
 24 MR. BANKSTON: But I really only have one  
 25 question on it.

Page 67

1 MS. AHMANN: Let me take a look.  
 2 BY MR. BANKSTON:  
 3 Q. And Mr. Bergstrom, I'm just wondering,  
 4 have -- do you have memory of ever seeing this?  
 5 A. I would have seen it, yes.  
 6 Q. And do you remember ever being instructed to  
 7 draft talking points discrediting this study?  
 8 MS. AHMANN: Object to form.  
 9 A. I don't remember being asked to develop  
 10 talking points specifically to discredit. We would  
 11 have developed talking points that the sales used --  
 12 our sales team could use in response to the article.  
 13 Q. You would agree with me that, with regard to  
 14 literature that was critical of forced-air warming  
 15 from the standpoint of orthopedic infections, it was a  
 16 goal of the marketing department to discredit those  
 17 studies.  
 18 A. I don't believe "discredit" is the right  
 19 word, no.  
 20 Q. Okay.  
 21 A. I believe the goal of the marketing  
 22 department was to review those papers, as we would any  
 23 paper, examine the strengths and weaknesses and then  
 24 provide the responses that our -- our sales force  
 25 could use.

Page 68

1 Q. Okay.  
 2 (Exhibit 92 was marked for  
 3 identification.)  
 4 BY MR. BANKSTON:  
 5 Q. Mr. Bergstrom, I've handed you Exhibit 92,  
 6 which is entitled "Forced-Air warming blowers: An  
 7 evaluation of filtration adequacy and airborne  
 8 contamination emissions in the operating room." Do  
 9 you recall ever seeing this study?  
 10 A. I would have seen it and I would have read  
 11 through it, yes.  
 12 Q. Were --  
 13 Did you ever recall being given instructions  
 14 to draft talking points on this study?  
 15 A. Yes, we would have -- our team would have  
 16 drafted talking points.  
 17 Q. And again, on this question again, was it a  
 18 goal of your department to discredit this study?  
 19 A. It was to provide our sales reps with  
 20 responses on how to address concerns about the  
 21 misinformation.  
 22 Q. Okay.  
 23 (Exhibit 93 was marked for  
 24 identification.)  
 25 BY MR. BANKSTON:

Page 69

1 Q. Mr. Bergstrom, I've handed you another  
 2 study, Exhibit 93. This study is entitled "Forced-Air  
 3 warming and ultra-clean ventilation do not mix." Do  
 4 you recall ever seeing this study?  
 5 A. Yes, I would have seen this.  
 6 Q. Do you recall being instructed to draft  
 7 talking points to your customers about this study?  
 8 A. Myself and the team would have drafted  
 9 talking points again to -- to address the  
 10 misinformation.  
 11 Q. Okay. When you say "misinformation," those  
 12 talking points would have been critical of this study.  
 13 A. There are some that are critical in terms of  
 14 the -- the way this study was set up and things that  
 15 were -- were overlooked and not -- not included, yes.  
 16 Q. Okay.  
 17 (Exhibit 94 was marked for  
 18 identification.)  
 19 BY MR. BANKSTON:  
 20 Q. Mr. Bergstrom, I've handed you Exhibit 94, a  
 21 scientific study entitled "Do forced air patient-  
 22 warming devices disrupt unidirectional downward  
 23 airflow?" Do you recall ever seeing this study?  
 24 A. Yes, I would have read this study.  
 25 Q. Okay. Do you recall being instructed to

18 (Pages 66 to 69)

## CONFIDENTIAL

Page 70

1 draft talking points critical of this study?  
 2 A. I likely would have directed talking points  
 3 the sales reps could use to respond to concerns about  
 4 the misinformation.

5 Q. Okay.  
 6 (Exhibit 95 was marked for  
 7 identification.)

8 BY MR. BANKSTON:

9 Q. I have handed you what's been marked as  
 10 Exhibit 95. This is a scientific study entitled  
 11 "Effect of forced-air warming on the performance of  
 12 operating theatre laminar flow ventilation." Do you  
 13 recall receiving this study?

14 A. Yes, I would have read it.

15 Q. Were you also instructed on this study to  
 16 draft talking points critical of the study?

17 A. I would have drafted -- myself and the team  
 18 would have drafted talking points again for the sales  
 19 reps to use to address this study's shortcomings and  
 20 misinformation provided.

21 Q. Okay.  
 22 (Exhibit 96 was marked for  
 23 identification.)

24 BY MR. BANKSTON:

25 Q. Mr. Bergstrom, I've handed you Exhibit 96,

Page 72

1 BY MR. BANKSTON:

2 Q. Mr. Bergstrom, I've handed you Exhibit 98, a  
 3 scientific study entitled "Forced-Air Warming Design:  
 4 Evaluation of Intake Filtration, Internal Microbial  
 5 Buildup, and Airborne-Contamination Emissions." Were  
 6 you provided a copy of this study?

7 A. I was provided a copy of this study --

8 Q. And --

9 A. -- and would have -- would have prep -- done  
 10 talking points to address the misinformation.

11 Q. I'm glad you're already anticipating here.  
 12 Let's move on to our final one.

13 (Exhibit 99 was marked for  
 14 identification.)

15 BY MR. BANKSTON:

16 Q. I have now handed you Exhibit 99, a  
 17 scientific study entitled "Infection control hazards  
 18 associated with the use of forced-air warming in  
 19 operating theatres." Were you provided a copy of this  
 20 study?

21 A. Yes, I would have reviewed this study.

22 Q. Okay. And with this study, you would have  
 23 also drafted talking points critical of the study.

24 A. Yes, I believe we drafted talking points.

25 Q. Okay. You now have in front of you --

Page 71

1 another scientific study entitled "Forced-air patient  
 2 warming blankets disrupt unidirectional airflow."  
 3 Were you provided a copy of this study at any time?

4 A. I would have read this study, yes.

5 Q. And likewise, you were also instructed to  
 6 draft talking points critical of this study.

7 A. I would have addressed talking points to  
 8 address misinformation, yes.

9 Q. Okay.  
 10 (Exhibit 97 was marked for  
 11 identification.)

12 BY MR. BANKSTON:

13 Q. I've now handed you Exhibit 97, a scientific  
 14 study entitled "Patient Warming Excess Heat: The  
 15 Effects of Orthopedic Operating Room Ventilation  
 16 Performance." Do you recall ever receiving a copy of  
 17 this study?

18 A. Yes, I would have reviewed this study.

19 Q. And you were instructed to draft talking  
 20 points critical of this study; correct?

21 A. I would have addressed talk -- or addressed  
 22 talking points -- provided talking points to, again,  
 23 address the misinformation that's included.

24 (Exhibit 98 was marked for  
 25 identification.)

Page 73

1 A. Not to be critical, to address  
 2 misinformation.

3 Q. Okay. I believe you now have nine published  
 4 scientific studies in front of you; correct?

5 A. There are nine, yes.

6 Q. From your testimony, I take it it is -- you  
 7 have been led to the conclusion that all nine of these  
 8 studies contain misinformation about your product.

9 MS. AHMANN: Object to form.

10 A. Our clinic -- our clinical team has gone  
 11 through these papers, identified various points of  
 12 weakness, and made me aware of those, yes.

13 Q. Okay. So your clinical team would make you  
 14 aware of weaknesses in these papers, but you have no  
 15 independent memory of being made of weaknesses in  
 16 Huang, Moretti or Zink.

17 A. It may have been in, like I said, the study  
 18 summary sheets that were -- were issued. I don't  
 19 recall seeing that, but --

20 Q. Okay.

21 (Discussion off the stenographic record.)  
 22 (Exhibit 100 was marked for  
 23 identification.)

24 BY MR. BANKSTON:

25 Q. Mr. Bergstrom, I've handed you Exhibit 100,

19 (Pages 70 to 73)

## CONFIDENTIAL

<p style="text-align: right;">Page 94</p> <p>1 they can share with customers.  2 Q. Okay. Now the exhibit I have handed you now  3 is a November 4th, 2008 set of talking points that  4 came out of your department. I'm wondering if you  5 remember this Kimberger study?  6 A. I don't remember the study. I don't  7 remember actually developing these talking points  8 either.  9 Q. Okay. Do you see where it has a discussion  10 of authorship and sponsorship?  11 A. Yes, I do.  12 Q. Okay. And it says there in the middle of  13 that paragraph, "ABAD was not listed as a sponsor..."  14 Who is ABAD?  15 A. That's Augustine Biomedical + Design.  16 Q. Okay. That is your competitor.  17 A. Dr. Augustine.  18 Q. Dr. Augustine. Okay.  19 And it states here that they were not a  20 sponsor, they had donated some equipment, "...and the  21 authors disclaim any involvement of the sponsors in  22 the preparation of the paper..." The next sentence in  23 bold says, "Certain portions of the paper read like  24 ABAD talking points; could they have assisted as  25 non-sponsors?" Do you see that?</p>	<p style="text-align: right;">Page 96</p> <p>1 the independence of the study's authors and the  2 company that may or may not have been involved in it?  3 A. I think the question as written is saying  4 it's an area to look into further.  5 Q. And why would you want to look into that?  6 MS. AHMANN: Object to form.  7 A. You know, these -- I'm --  8 It's not my area of expertise. I don't  9 know.  10 Q. Well if the sponsor participated in the  11 drafting of the paper, --  12 A. Uh-huh.  13 Q. -- could that raise questions about the  14 independence of the scientists from the company?  15 A. Potentially, yes.  16 Q. Okay.  17 THE REPORTER: We have to change disks. Off  18 the record, please.  19 (Recess taken.)  20 BY MR. BANKSTON:  21 Q. Mr. Bergstrom, before we went on break we  22 had been talking about various studies, and I  23 believe -- you know, you've told me numerous times it  24 was never your intention to discredit this -- these  25 studies, it's always been your intention to prevent</p>
<p style="text-align: right;">Page 95</p> <p>1 A. I do.  2 Q. Okay. Can you tell me why that might be  3 relevant or important?  4 MS. AHMANN: Object to the form.  5 A. It seems like a question that is -- is being  6 asked. I don't know that these are final talking  7 points. Perhaps they were submitted for review and  8 that's a question that they wanted to rectify.  9 Q. So at this point there's no real indication  10 that your competitor was a sponsor of this paper, but  11 there's still some concern that they could have  12 assisted in the drafting or creation of this study.  13 Does that raise any concern to you?  14 MS. AHMANN: Does what? Does what raise a  15 concern?  16 Q. The statement I just made, that they are not  17 listed as a sponsor but could have potentially  18 assisted in the preparation of the paper. Does that  19 raise any concern to you?  20 A. With me, not necessarily. But again, it's  21 not my -- this isn't my -- clinical studies and what's  22 involved in conducting a clinical study isn't -- isn't  23 in my arena and scope.  24 Q. Would you agree with me that what is being  25 communicated here is that there may be questions about</p>	<p style="text-align: right;">Page 97</p> <p>1 misinformation. Is that right?  2 A. That is accurate, yes.  3 Q. All right. Can -- can you define for me  4 what you mean when you say "misinformation?" What --  5 what does that include?  6 A. I would include in that some of the -- the  7 shortcomings of the study. And it's not necessarily  8 the studies themselves or even the authors, it's the  9 way the studies were used. A lot of times what was  10 being promoted out into the -- into the hospitals  11 and -- and clinicians was inaccurate and not supported  12 by the studies.  13 Q. In other words, taking stuff out of context,  14 giving less than the full story, that's a form of  15 misinformation; right?  16 A. It can be when part of a larger -- in a  17 larger campaign that -- that --  18 Yes.  19 Q. Omitting pertinent details of a study, that  20 would be a form of misinformation.  21 A. Depending on the relevance. I mean it  22 depends on what, I suppose, is included, so --  23 Q. Or, for instance, misrepresenting weaknesses  24 in study design, things like that, that could be  25 misinformation.</p>



## CONFIDENTIAL

<p style="text-align: right;">Page 98</p> <p>1 A. Potentially, yes.</p> <p>2 Q. Okay. Picking and choosing only the parts</p> <p>3 that support your views, that could be a form of</p> <p>4 misinformation.</p> <p>5 A. I'd have to see examples --</p> <p>6 Q. Okay.</p> <p>7 A. -- before I could speak to that.</p> <p>8 Q. Not disclosing things about the authors and</p> <p>9 their independence, that would also be a form of</p> <p>10 misinformation that should be avoided.</p> <p>11 A. Again, potentially. I would need to see</p> <p>12 examples.</p> <p>13 Q. Okay. And customers should never be given</p> <p>14 misinformation; correct?</p> <p>15 A. I would say it's not an ideal way to go</p> <p>16 about your business.</p> <p>17 Q. Sure. And tell me why that is.</p> <p>18 A. It doesn't -- I mean it doesn't serve a -- a</p> <p>19 benefit to the business to not -- to provide</p> <p>20 information that's incorrect.</p> <p>21 Q. Well apart from the benefit or advantage or</p> <p>22 disadvantage to the benefit, there are patients out</p> <p>23 there; right?</p> <p>24 A. Yes.</p> <p>25 Q. Those patients could get hurt if there's</p>	<p style="text-align: right;">Page 100</p> <p>1 would intentionally provide misinformation.</p> <p>2 Q. Okay. I'm going to talk a little bit more</p> <p>3 about talking points and how those get created, and so</p> <p>4 I'd like to show you something here.</p> <p>5 (Discussion off the stenographic record.)</p> <p>6 (Exhibit 107 was marked for</p> <p>7 identification.)</p> <p>8 BY MR. BANKSTON:</p> <p>9 Q. Mr. Bergstrom, I've handed you a February</p> <p>10 25th, 2010 document entitled "Arizant forced-air</p> <p>11 warming and SSI prevention: Talking points for</p> <p>12 sales." This document begins with a description of</p> <p>13 "Our position (please know this word for word)," and</p> <p>14 I'm taking this is information that you want your</p> <p>15 salespeople to be able to communicate to their</p> <p>16 customers.</p> <p>17 MS. AHMANN: Objection, lack of foundation.</p> <p>18 A. Potentially that's what they were developed</p> <p>19 for. I'm --</p> <p>20 I know this was developed by Hal Gray, I</p> <p>21 believe, who is our international -- was in our</p> <p>22 international business.</p> <p>23 Q. Okay.</p> <p>24 A. And I don't know that these were released or</p> <p>25 if this is a draft or -- or --</p>
<p style="text-align: right;">Page 99</p> <p>1 misinformation; right?</p> <p>2 A. Potentially, yes.</p> <p>3 Q. That's not something the company would ever</p> <p>4 want to have happen.</p> <p>5 A. No. Patient safety is our top priority.</p> <p>6 Q. And in -- and in some ways, your role is</p> <p>7 kind of to protect customers from misinformation;</p> <p>8 is -- wouldn't you agree?</p> <p>9 MS. AHMANN: Object to form.</p> <p>10 A. I --</p> <p>11 In the information we communicate, yes.</p> <p>12 Q. I mean, in other words, you see a lot of</p> <p>13 information in your day-to-day job and you can't</p> <p>14 communicate all of it to the customer; correct?</p> <p>15 MS. AHMANN: Object to form.</p> <p>16 A. Yes. I mean we certainly can't communicate</p> <p>17 everything.</p> <p>18 Q. You -- you'd agree with me that the customer</p> <p>19 relies on you to a certain extent to find them what is</p> <p>20 pertinent and relevant and clear up misinformation.</p> <p>21 That's part of your job; right?</p> <p>22 A. It would probably be part, yes.</p> <p>23 Q. And -- and in that job, 3M would never want</p> <p>24 to provide misinformation.</p> <p>25 A. I -- yeah. I can't think of a reason why we</p>	<p style="text-align: right;">Page 101</p> <p>1 Q. Okay. In that first sentence where it says,</p> <p>2 "There is no evidence that forced-air warming</p> <p>3 increases the risk of surgical site infections (SSIs),</p> <p>4 increases bacterial contamination in operating</p> <p>5 theaters, or interferes with laminar flow in operating</p> <p>6 theaters," do you see that sentence?</p> <p>7 A. I do.</p> <p>8 Q. Okay. And I kind of want to concentrate on</p> <p>9 the last little bit of it where it says "interferes</p> <p>10 with laminar flow," that there's no evidence that</p> <p>11 forced-air warming increases the risk of interference</p> <p>12 with laminar flow. Do you agree with that statement?</p> <p>13 A. I think I would have probably made the claim</p> <p>14 that it --</p> <p>15 "Interferes" is a challenging word because</p> <p>16 ev -- everything -- a lot of things in the OR will</p> <p>17 cause minor disruptions in laminar flow, --</p> <p>18 Q. Okay.</p> <p>19 A. -- from the lamps to the personnel to any</p> <p>20 number of things. So whether that disruption is</p> <p>21 significant or not, that hasn't been proven.</p> <p>22 Q. Okay. You remember when we went through the</p> <p>23 stack of studies that you had been seeing and directed</p> <p>24 to draft talking points on.</p> <p>25 A. Yes.</p>

## CONFIDENTIAL

<p style="text-align: right;">Page 162</p> <p>1 patients warmed, all the clinical studies and 2 research. 3 Q. To be fair, of those 200 million patients 4 warmed, not all 200 million are orthopedic patients; 5 are they? 6 A. No, they're not. 7 Q. And of those orthopedic patients, a 8 substantial number, enough to be statistically 9 significant, developed post-surgical infections while 10 the Bair Hugger was being used. 11 A. I couldn't tell you how many or if it was 12 statistically significant. 13 (Discussion off the stenographic record.) 14 Q. Let's move on. I just want to know, sitting 15 here today now, 2016, does the company recognize the 16 theoretical risks from forced-air warming devices? 17 A. I believe the theoretical risks come from 18 the Augustine campaign, and it's -- it's theoretical, 19 it hasn't been proven, it's been promoted that way by 20 a competitor. 21 Q. Okay. 22 (Exhibit 118 was marked for 23 identification.) 24 BY MR. BANKSTON: 25 Q. I have handed you Exhibit 118, which is</p>	<p style="text-align: right;">Page 164</p> <p>1 Q. Okay. Professor Leaper over the years has 2 been involved in some published literature that has 3 implicated a risk from forced-air warming; correct? 4 A. He has published papers on that topic, yes. 5 Q. Okay. Now in the "Positioning" section 6 under that second bullet it says, "Professor Leaper is 7 using his stature to promote unsubstantiated and 8 erroneous claims with the intent to mislead 9 customers..." Do you agree with that statement? 10 A. I'm not familiar enough with Professor 11 Leaper to make a call one way or another on him. 12 Q. When that was brought up in this meeting, 13 was that something you wanted to look further into? 14 A. It wasn't -- I don't -- don't believe it was 15 my idea. I think it was, again, just something that 16 was added to the list. 17 Q. It's in fact the very first thing on the 18 list; right? 19 A. He's the first topic, yes. 20 Q. And in fact, part of the plan here is to try 21 to tarnish his reputation; correct? 22 A. It was a tactic that was considered. Again, 23 I go -- I go back to the "Ideas" column, which to me 24 says these are more of a collection of ideas than any 25 kind of action list.</p>
<p style="text-align: right;">Page 163</p> <p>1 marked as a Response Communication Plan. 2 A. Yes. 3 Q. Are you familiar with how this process 4 works, developing a Response Communication Plan? 5 A. I mean I think -- at this point I think this 6 was more of a -- an initial brainstorm or at least a 7 collection of ideas in different ways we could -- 8 could proceed. 9 Q. I'm -- I'm wondering where we're getting the 10 idea that this was a brainstorm rather than a plan. 11 A. Just from knowledge that a lot of these -- 12 these tactics weren't ever implemented, so it's more 13 of a collection of -- of possible tactics -- 14 Q. Okay. 15 A. -- than any kind of plan on what we're 16 doing. 17 Q. See the very first line of this document, it 18 has it separated out into "Initiative," "Goals," 19 "Ideas," "Positioning" in each of these columns. 20 A. Yes. 21 Q. And the first column, the first initiative 22 says "Leaper." Do you -- am -- 23 Am I correct that this is referring to 24 Professor David Leaper? 25 A. Yes, I believe that's accurate.</p>	<p style="text-align: right;">Page 165</p> <p>1 Q. Okay. That was certainly an idea y'all had 2 then; right? 3 A. We have had many, many, many different 4 ideas. That doesn't mean we acted on them. 5 Q. And I think part of the reason you would 6 want to make clear that you didn't act on them is 7 because this is not exactly the most tasteful thing to 8 do; -- 9 MS. AHMANN: Object to form. 10 Q. -- correct? 11 A. I think we just chose a different direction. 12 Q. I mean -- 13 And that different direction was not to go 14 out and attempt to tarnish a man's professional 15 reputation. Is that what you're saying? 16 MS. AHMANN: Object to form. 17 A. I'm saying that ultimately we decided not to 18 proceed with that. 19 Q. I'm asking you here today, apart from Dr. 20 Leaper, in a general sense -- 21 You remember we talked about that positive, 22 high-road message? 23 A. Uh-huh. 24 Q. Is it -- is it generally a thing that you 25 would want to pursue, to go after somebody's</p>



# **EXHIBIT 30**

3M Health Care Business Group  
3M Center, Bldg. 275-05W-06  
St. Paul, MN 55144-1000  
651 733 1110

December 1, 2016



**Via E-Mail and Overnight Delivery**

Dr. Michael Dutcher  
District Director  
Food and Drug Administration, Minneapolis District Office  
250 Marquette Avenue South, Suite 600  
Minneapolis, MN 55401

Dear Dr. Dutcher:

I am writing to clarify a statement made by the investigator in FDA's Establishment Inspection Report (EIR) following an inspection of Arizant between November 30, 2009 and January 6, 2010. (Arizant was the company manufacturing the Bair Hugger system at the time. 3M acquired the Bair Hugger product line in October 2010.)

We recently reviewed FDA's EIR from that inspection investigating a trade complaint regarding potential microbial contamination. In that inspection, FDA examined complaints from January 2006 through the time of the inspection, and found none that revealed any reports of microbial air contamination. FDA also reviewed several independently conducted studies which conclude that forced air warming systems do not increase bacterial contamination in the operating room. FDA found no evidence to support the complaint allegations.

We notice, however, that the EIR, p. 4, describes the Bair Hugger devices as having a "0.2  $\mu$ m HEPA filter." The Bair Hugger units have never had a "HEPA" filter as that term is defined by industry standards. It is accurate to say that the Bair Hugger units have filters that perform consistently with the American Society of Heating Refrigeration and Air Conditioning Engineers (ASHRAE) standards for operating room ventilation systems (MERV rating 14-16). 3M reviewed the documents Arizant provided to the FDA during the 2009 – 2010 inspection and at prior inspections, and did not find documents indicating that the Bair Hugger devices have a HEPA filter. Records provided during the inspection, within product literature and documenting internal product specifications describe the filter as "0.2  $\mu$ m" with no "HEPA" designation.

Your correction of the record is appreciated. Please let me know if you have any questions regarding this request.

Sincerely,

A handwritten signature in blue ink that reads "Suzanne M. Danielson". The signature is fluid and cursive, with a large, stylized "S" and "D".

Suzanne M. Danielson, Director  
Regulatory Affairs and Quality Compliance  
3M Health Care Business Group  
3M Center, Bldg. 275-05W-06 Room 5B09  
Saint Paul, MN 55144-1000

SMD/ljl